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(54) Dietary supplement for neuropaths

(57) The present invention relates to a dietary supplement comprising balanced amounts of natural substances having neuro-protective activity such as α-lipoic acid and γ-linolenic acid or soy-bean phospholipids, a substance having anti-inflammatory and antioxidant activity such as selenomethionine, a substance having saccharo- and lipometabolism regulating activity such as chromium picolinate, antioxidant vitamins such as vitamin C and vitamin E, together with complex B vitamins having neurotrophic activity.

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Description

[0001] The present invention relates to a dietary supplement and particularly to a composition of substances particularly useful to be given to subjects affected by neuropathies.

[0002] It is known that in many cases the dietary supplements are formulated so as to result useful to be given to persons prone to particular deficiency situations or in conditions of increased need of specific nutrients.

[0003] The object of the present invention is to provide a dietary supplement particularly useful in the diet in subjects affected by neuropathies. This object is achieved according to the present invention with a composition of substances already known in themselves, but combined in a new and opportunely balanced way to be given in the diet of persons having the aforesaid needs.

[0004] The features of the dietary supplement are specified in claim 1, other features are specified in the depending claims.

[0005] The dietary supplement according to the present invention besides being easily usable, has the basic advantage of providing the consumer with an aggregate of substances each having a well determined activity and being mutually dosed in an optimal way. It comprises in fact well determined and opportunely coordinated amounts of two substances having a neuroprotective activity, a substance having anti-inflammatory and antioxidant activity, a substance acting on the saccharo- and lipometabolism, as well as vitamins with antioxidant properties and a vitamin complex acting on neuronal trophism.

[0006] The first substance having neuro-protective activity, opportunely selected for the dietary supplement according to the present invention, is lipoic or thioctic acid, a natural substance whose properties are already known and thus it does not require a detailed description. It is present in the composition in amounts comprised between 50 and 600 mg, preferably between 100 and 300 mg, according to the intake dose and/or dispensing form.

[0007] The second substance having a neuro-protective activity that is used in the composition according to the present invention is γ-linolenic acid, a polyunsaturated fatty acid whose properties are already known and thus a detailed description is not necessary for it. It is present in the composition in amounts comprised between 50 and 600 mg, preferably between 100 and 300 mg, depending on the intake dose and/or dispensing form.

[0008] γ-linolenic acid can possibly be replaced by equivalent amounts of the phospholipid fraction of the soy-bean lecithin that is phosphatidylserine, phosphatidylcholine and phosphatidylethanolamine.

[0009] As a substance having anti-inflammatory and antioxidant activity, selenium is employed, preferably as selenomethionine comprising 40.26% selenium, in amounts comprised between 0.05 and 0.11 mg, preferably between 0.06 mg and 0.1 mg depending on the intake dose and/or dispensing form.

[0010] In some embodiments of the dietary supplement according to the present invention, as a substance having saccharo- and lipometabolism regulating activity chromium picolinate is used comprising 12.43% Cr. Also the properties of this substance are already known and thus a detailed description is not necessary. It is present in the composition in amounts comprised between 0.4 and 1.6 mg preferably between 0.4 and 0.8 mg, depending on the intake dose and/or dispensing form.

[0011] Chromium picolinate can possibly be replaced by equivalent amounts of another organic compound of chromium.

[0012] As antioxidant vitamins in the composition according to the present invention, vitamins C and E are employed. Vitamin C is introduced in the composition preferably in the form of pure crystals in amounts comprised between 60 and 180 mg, preferably between 90 and 120 mg depending on the intake dose and/or dispensing form.

[0013] Vitamin E is present in the composition preferably in the form of 50% powder and in amounts comprised between 1.5 and 30 mg, preferably between 10 and 30 mg depending on the intake dose and/or dispensing form.

[0014] Moreover, as a substance acting on neuronal trophism, is present in the composition a vitamin complex of group "B", particularly vitamin B1 in the dosage from 0.21 to 2.1 mg, preferably between 1 and 2 mg; vitamin B2 in the dosage from 0.34 to 2.4 mg, preferably between 1 and 2.2 mg, vitamin B6 in the dosage from 0.3 to 3 mg, preferably between 1 and 3 mg, and vitamin B 12 in the dosage from 0.00035 mg to 0.015 mg, preferably between 0.00075 and 0.0015 mg.

[0015] Depending on the intake dose and/or dispensing form, the dietary supplement according to the present invention can also comprise excipients, fragrances and other substances having a known activity for the desired purpose. Such substances are for example maltodextrin, microcrystalline cellulose, magnesium stearate, colloidal silica, etc. Even the optimal amounts of such substances are to be selected each time depending on the dosage and on the dispensing way of the dietary supplement according to the present invention.

[0016] Even the preparation technique of the composition according to the present invention is chosen in function of the dispensing way and of other practical considerations. This will be more evident to those skilled in the art from the following embodying example of the present invention.

[0017] For the realization of the following operative examples commercially available substances have been used . As α-lipoic acid a product provided by Labochim S.r.1. of Milan has been used; as γ-linolenic acid a product provided from Gielepi Chemicals of Milan has

been used, which society has also provided chromium and selenium mineral salts, whereas the substances having vitaminic action have been provided by Istituto delle Vitamine Roche.

EXAMPLE 1

Soft gelatin capsules

[0018] For the preparation of a dietary supplement according to the present invention in the form of soft gelatin capsules , the different components necessary for the production of an industrial lot of about 150.000 capsules wherein the weight content of the gelatin was about 35%, were separately weighed.

[0019] In a stainless steel dissolver provided with stirrer holding about 200 liters, were first introduced γ-linolenic acid, soy-bean lecithin, monodiglycerides of fatty acids followed by all other powdery components under slow stirring.

[0020] After a period of about 15 minutes an homogeneous suspension was obtained which was used to fill the soft gelatin capsules through a proper and specific plant working in aseptic environment.

[0021] The production plant of soft gelatin capsules worked on the solidification principle of animal gelatin in bands of different width and thickness. The formation of capsules and the relevant sealing was simultaneous with the filling of same by means of suitable moulds. The size of the capsule was an oval 12.

[0022] The weight per cent composition of each capsule was finally as follows:

Gelatin	34.3
γ-linolenic acid	25
α-lipoic acid R/S	30
Vitamin C	4.50
Monodiglycerides	2.80
Vitamin E 50%	1.50
Soy-bean lecithin	1
Selenomethionine	0.01
Pantothenic acid	0.45
Vitamin B2	0.15
Vitamin B1	0.12
Vitamin B6	0.11
Vitamin B12	0.00015

[0023] The thus obtained soft gelatin capsules, after an appropriate maturing period, were packaged in PVC-ALU blisters or in glass bottles.

EXAMPLE 2

Soft gelatin capsules

[0024] To make the dietary supplement more suitable to be taken by subjects suffering from saccharometabolism disorders, it was prepared acting as in example 1, but with chromium supply in the form of chromium picolinate.

[0025] In a stainless steel dissolver provided with stirrer holding about 200 liters, γ-linolenic acid, soy-bean lecithin, monodiglycerides of fatty acids were first introduced and followed by all other powdery components under slow stirring.

[0026] After a period of about 15 minutes an homogeneous suspension was obtained which was used to fill the soft gelatin capsules through a proper and specific plant working in aseptic environment.

[0027] The production plant of soft gelatin capsules worked on the solidification principle of animal gelatin in bands of different width and thickness. The formation of capsules and the relevant sealing occurred simultaneously with the filling of same by means of suitable moulds. The size of the capsule was an oval 12.

[0028] The final composition of each capsule expressed as a per cent weight was as follows:

Gelatin	34.3
γ-linolenic acid	25
α-lipoic acid R/S	30
Vitamin C	4.50
Monodiglycerides	2.80
Vitamin E 50%	1.50
Soy-bean lecithin	1
Selenomethionine	0.01
Pantothenic acid	0.45
Vitamin B2	0.15
Vitamin B1	0.12
Vitamin B6	0.11
Vitamin B12	0.00015
Chromium picolinate	0.08

[0029] The thus obtained soft gelatin capsules, after an appropriate maturing period, were packaged in PVC-ALU blisters or in glass bottles.

EXAMPLE 3

Coated swallowable tablets

[0030] To prepare a dietary supplement in the form of coated swallowable tablets the different components necessary for the production of an industrial lot of about 200.000 capsules were separately weighed.

[0031] In a Viani type mixer there were thoroughly mixed for about 10 minutes all components according to the present invention. The so obtained mixture was compressed with a Ronchi R23 machine equipped with an electronic device for the control of the unitary weight and provided with suitable oval or circular punches.

[0032] The so obtained tablets, weighing about 600

mg, were left for about 48 hours on suitable trellises in a dehumidified room.

[0033] The coating of the tablet was carried out in a rotating tray which, to avoid the fusion and consequent polymerization of α-lipoic acid, was heated at temperatures not higher than 40°C.

[0034] The coating was accomplished through a suspension of hydroxypropylmethylcellulose, dyes, titanium dioxide and suitable excipients. The final weight of the tablet was 630 mg +/- 20 mg.

[0035] The final composition of each capsule expressed as a per cent weight was as follows:

Microcrystalline cellulose	36.32
Racemic α-lipoic acid	47.37
Selenomethionine	0.01
Pantothenic acid	0.71
Vitamin B2	0.24
Vitamin B1	0.19
Vitamin B6	0.17
Vitamin C	7.11
Vitamin E 50	2.37
Hydroxypropylmethylcellulose	3.16
Magnesium stearate	0.79
Titanium dioxide	1.58

EXAMPLE 4

Coated swallowable tablets

[0036] There was followed the same procedure as in example 3, but with chromium supply in the form of chromium picolinate in order to make the dietary supplement more suitable to be taken by subjects suffering from saccharometabolism disorders.

[0037] The final composition of the capsule in % of its weight was as follows:

Microcrystalline cellulose	36.32
Racemic α-lipoic acid	47.37
Selenomethionine	0.01
Pantothenic acid	0.71
Vitamin B2	0.24
Vitamin B1	0.19
Vitamin B6	0.17
Vitamin C	7.10
Vitamin E 50	2.37
Chromium picolinate	0.13
Hydroxypropylmethylcellulose	3.15
Magnesium stearate	0.79
Titanium dioxide	1.58

EXAMPLE 5

[0038] There was followed the same procedure as in Example 2 with the difference that 25% of γ-linolenic acid was replaced by phospholipids of soy-bean lecithin in the amount of 10% with respect to the weight of the capsule.

Claims

1. A dietary supplement for neuropaths **characterized in that** it comprises balanced amounts of a first substance having neuro-protective activity, a second substance having a neuro-protective activity too, a substance having anti-inflammatory and antioxidant activity, a substance having saccharo- and lipometabolism regulating activity as well as vitamins having antioxidant activity and vitamins of complex B having neurotrophic activity.

2. A dietary supplement according to claim 1, **characterized in that** the first substance having neuro-protective activity is α-lipoic acid.

3. A dietary supplement according to claim 1, **characterized in that** the second neuro-protective substance is γ-linolenic acid.

4. A dietary supplement according to claim 1, **characterized in that** the second neuro-protective substance is the phospholipidic fraction of the soy-bean lecithin.

5. A dietary supplement according to the previous claims, **characterized in that** the substance having anti-inflammatory and antioxidant activity is selenomethionine.

6. A dietary supplement according to the previous claims, **characterized in that** the substance having saccharo- and lipometabolism regulating activity is chromium picolinate.

7. A dietary supplement according to one or more previous claims, **characterized in that** as antioxidant vitamins there are used vitamin C and vitamin E.

8. A dietary supplement according to one or more previous claims, **characterized in that** the substance having activity on neuronal trophism is a group B vitamin complex .

9. A dietary supplement according to claim 7, **characterized in that** the group B vitamin complex comprises vitamin B1, vitamin B2, vitamin B6 and vitamin B12.

10. A dietary supplement according to the previous claim, **characterized in that** vitamin B1 is present in the vitamin complex in a dosage from 0 to 21 mg,

vitamin B2 is present in a dosage from 0.34 to 2.4, vitamin B6 is present in a dosage from 0.3 to 3 mg and vitamin B12 is present in a dosage from 0.00033 to 0.0015 mg.